

RCE AGM Presentation

30 November 2020

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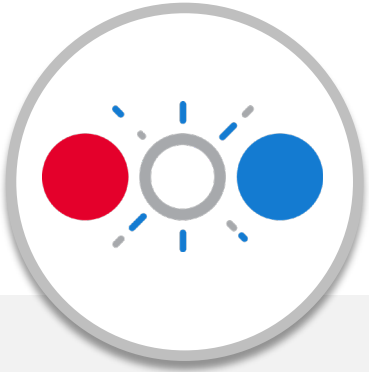
About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals (ASX:RCE) is commercialising a New Class of Synthetic Anti-Infectives to address the global health issue of antibiotic resistant superbugs and emerging viral pathogens.



Listed on ASX 2016
(ASX:RCE)

Unique and universal
Mechanism of Action

Water soluble over a broad range of pH levels

New Class of Synthetic Anti-Infectives that kill emerging viral pathogens as well as Gram + & Gram – bacteria, including their superbug forms - even with repeated use!

RECCE® 327 & RECCE® 435 – bacterial indications

RECCE® 529 – viral indications

RECCE® 327 awarded Qualified Infectious Disease Product designation under GAIN Act

10 years market exclusivity (post approval)

Fast track (life of regulatory process)

Patented manufacturing, producing to **Phase I & II volumes**

Board and Management Structure

Dr John Prendergast – Non-Executive Chairman
BSc (Hons), MSc (UNSW), PhD (UNSW), CSS (HU)
US based, current Chairman and Co-founder of Palatin Technologies, Inc. (NYSE: PTN) and Lead Director of Heat Biologics, Inc. (NASDAQ: HTBX) – extensive experience in the international commercialisation of pharmaceutical technologies

James Graham – Managing Director & Chief Executive Officer
BCom (Entrepreneurship), GAICD
5 years as former Executive Director
Invested along-side shareholders in most capital rounds since inception.
Background in marketing, business development and commercialisation of early-stage technologies.

Dr Alan Dunton – Non-Executive Director
BSc (BioChem) Hons, M.D. (NYU)
US based, Director of Palatin Technologies. Over three decades of senior pharmaceutical experience incl. President and MD of Janssen Research Foundation (J&J Research). Dr Dunton has advanced a number of blockbuster antibiotics through regulatory review and commercialization at fortune 500 companies including J&J and Roche.

Michele Dilizia – Executive Director & Chief Scientific Officer
BSc (Med Sci), Grad Dip Bus (Mkting), BA (Journ), GAICD, MASM
Co-inventor and qualified medical scientist; specialisation in medical microbiology and regulatory affairs

Dr Justin Ward – Executive Director & Principal Quality Chemist
BSc (Chem), PhD (Chem), MRACI, CChem
A quality control expert who has worked with leading pharmaceutical companies, he is bringing Recce's research and development, and manufacturing up to US FDA requirements

Alistair McKeough – Company Secretary (Outsourced – **Automic Group)**
Alistair is a qualified lawyer and Principal of Automic Legal Pty Ltd, Alistair has broad experience as a commercial litigator and Company Secretary to ASX Listed companies

Justin Reynolds – CFO (Outsourced - **Pitcher Partners Sydney)**
Justin is a qualified accountant and Partner of Pitcher Partners Sydney, Justin has broad experience covering all areas of accounting, taxation and assurance. Particularly, Justin's areas of expertise are business services and outsourced accounting

Arthur Kollaras – Principal Engineer & Head of Manufacturing
BSc Beng (Chem), PhilEng (Enviro), MIEAust, MISPE
Highly qualified in chemical engineering and microbiology, has significant experience taking a new technology concept to pilot plant and full-scale FDA standards and production internationally

Dr David Bowers – Chair of Clinical Advisory Committee
Leading spinal injury physician at Royal North Shore Hospital. Dr Bowers has a specialist interest in the treatment of complex and life-threatening antibiotic resistant infections, particularly among patients with severe spinal cord injuries.

Professor Philip Sutton – Head of *H. pylori* Development Program
Global infectious disease expert with over 30 years of research and industry experience, having served as former Head of Immunology at CSL Ltd in Melbourne. Chief Editor of textbook "*Helicobacter pylori* in the 21st Century" and has co-authored 92 manuscripts published in peer-reviewed journals. Professor Sutton currently leads Mucosal Immunology Group at Murdoch Children's Research Institute.

A Crisis for New Anti-infectives - Facts & Figures

Anti-infective Portfolio
(Unmet Medical Needs)

Antibacterial
e.g. Sepsis, Burn Wounds, Gastric (*H. Pylori*)

Antiviral
e.g. SARS-CoV-2 (COVID-19), influenza

Antibiotic Resistance - The Superbug Crisis

>700,000
Each year 700,000 people died globally due to antimicrobial resistance[1]

>10 million
By 2050, it is believed that super bugs will kill up to 10 million people each year (this will supersede deaths projected from cancer) [2]

>2 million
Every year, 2 million people in the US get an antibiotic resistant infection, and at least 23,000 people die from it[3]

Data/Technology Synergies

WHO Coronavirus (COVID 19) Global Situation Dashboard[4]
November 28, 2020

61,299,371
confirmed cases (and growing…)

1,439,784
deaths

[1] *World Health Organisation (WHO)*
[2] *Jim O'Neill AMR Review Report*
[3] *Centre for Disease Control and Prevention*
[4] *WHO Coronavirus Disease (COVID-19) Dashboard*

RECCE® – Multiple Anti-Infective Applications

Recce Pharmaceuticals

Recce's technology enjoys the added opportunity of multiple markets and product categories.

INDICATION ▼ DISCOVERY ▼ PRE-CLINICAL ▼ FIH SAFETY & EFFICACY ▼ REGULATORY SUBMISSION ▼

Intravenous Administration

Phase I IV study subjects to be screened in Q4 2020

- Severe Sepsis - Blood poisoning
- Pre Sepsis - Kidney and UTI infections

Topical Administration

Phase I/II topical study HREC approved

- Skin and Skin Structure Infection - Wound Infection, Contraction

Viral Indications

R327 dispatched to CSIRO, R327 & R529 dispatched to Path BioAnalytics

- Influenza A and other significant respiratory infections
- R327 Priority 1 Candidate Group - SARS-CoV-2 Anti-viral Program with CSIRO and The Peter Doherty Institute
- Path BioAnalytics & leading US academic institution to evaluate R327 & R529 anti-viral activity in SARS-CoV-2

CSIRO · Path BioAnalytics · Doherty Institute · The University of Tennessee Health Science Center

Other Indications

New R435 to be tested against *H. pylori* with Murdoch Children's Research Institute

- Gastritis *(H. pylori)*
- Reproductive Organs *(N. gonorrhoeae)*

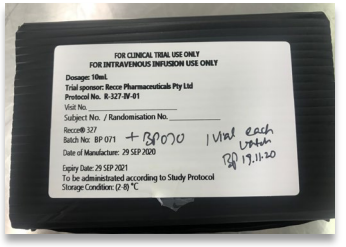
*FIH – First-in-human

Estimated timelines/indications are subject to change in development plans and regulatory requirements/clarifications

RECCE® 327 Phase I Human Clinical Trial

- **Human safety and tolerability study to assess IV infusion of RECCE® 327 in 48 healthy subjects as a single ascending dose**
- Phase I trial agreement with leading clinical research organization PAREXEL
- Trial will be held at CMAX Clinical Research – an independent trial facility
  - **Facility meets international regulatory authority data entry and quality requirements including European Medicines Agency and US FDA**
- Formal subject recruitment to open for enrolments shortly
  - CMAX has more than 30,000 registered patient volunteers on file
  - Patient screening Q1, 2021





Dispatched to Clinical Trial Facility (CMAX)
Placebo and RECCE 327 (I.V.) via Recce's Manufacturing facility (Sydney)



CMAX Phase I Clinical Unit

RECCE® 327 Phase I/II Topical Human Trial in burn wound infections

- **The topical study will assess RECCE® 327 as a broad-spectrum antibiotic for patients with Gram-positive and Gram-negative bacterial burn wound infections**
- Sponsored by the South Metropolitan Health Service, Department of Health, Government of Western Australia
  - **Fiona Stanley Hospital nominated as the study site**
  - **Principal Investigator Professor Fiona Wood**
  - **Dr Wood pioneered the innovative the worlds-first 'spray-on skin' technique, which greatly reduces permanent scarring in burns victims.**
- Over 14 days, 10 patients will receive RECCE® 327 daily while a further 20 receive treatment 3 times per week
- Phase I/II clinical trial approved by Human Research Ethics Committee



Government of **Western Australia**
South Metropolitan Health Service
Fiona Stanley Hospital

recce.com.au

RECCE® 435 Pre-clinical Studies Program with Helicobacter pylori

- **Murdoch Children's Research Institute (MCRI) to evaluate *in-vivo* antimicrobial activity of RECCE® 435 oral formulation against *Helicobacter pylori (H. pylori)* in pre-clinical studies program**
- **RECCE® 435 is a new broad-spectrum synthetic polymer antibiotic formulated for oral use**
- **Study led by *H. pylori* infectious disease expert Professor Philip Sutton**
- **Research program will be carried out by Mucosal Immunology Group at the MCRI Royal Children's Hospital**
  - **MCRI is one of the top three child health research institutes worldwide for research quality and impact**
- Recce and MCRI will work together on the oral antibiotic dosing program with a particular focus on optimal dosing and the effect of RECCE® 435
- Anticipated completion in approximately 12 months, at which time Recce will pursue a human clinical trial



Recce SARS-CoV-2 International Antiviral Program

- **RECCE® 327 compound selected as Priority 1 candidate group for testing in SARS-CoV-2 Antiviral Program.**
  - The program is run by CSIRO and The Peter Doherty Institute for Infection and Immunology.
  - R327 (only) was chosen by a Science Selection Panel including field experts in the areas of: Virology, Antivirals, Medicinal Chemistry & Clinical Trials of Antiviral drugs.
  - Therapeutic anti-viral treatment focus with added potential benefit against secondary bacterial infections.
  - All intellectual property rights are retained by the Company

- **RECCE® 327 and RECCE® 529 have shown concentration-dependent reductions in the SARS-CoV-2 virus**
  - Concentrations of R327 and R529 tested, further indicated an **excellent toxicity profile (<0.25%) on Vero (monkey) cells, in a separately related study**
  - COVID-19 studies will be **advancing** to gold-standard in-vivo animal models (e.g. ferret)
  - Method of administration will be via intranasal to target viral infection in the airways/lungs
  - Ferret international study has started, data expected within a month

Patents and trademarks

Recce's patent portfolio includes more than 15 issued patents and patent applications in the world's major markets, including the United States, Europe, Japan, China and Australia.

Patent Family 1 – Antimicrobial Polymers and Their Compositions

- Family 1 group relates to the Company's unique and highly economical manufacturing process and use of the polymer in treatment of diseases

Patent Family 2 – Copolymer for use in Method of Treatment of a Parenteral Infection

- Family 2 relates to the method of manufacture, administration and application to treat a broad range of common human infections.

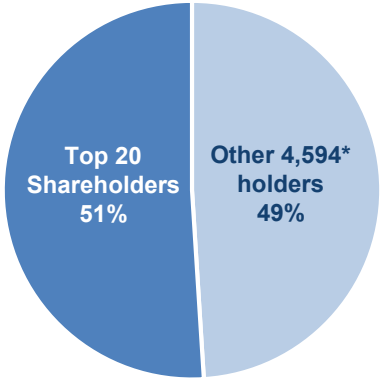
Patent Family 3 – Anti-Virus Agent and Method for Treatment of Viral Infection

- Family 3 relates to a method of treatment of a broad range of viral infections, particularly parenteral viral infection

Filed	Patent Family 1 Granted	Expiry	Patent Family 2	Expiry	Patent Family 3	Expiry	Patent Family 4	Trademarks registered
Australia	✓	2028	✓	2035	Pending	2037	Pending	✓
USA	✓	2029	✓	2035	Pending	2037	Pending	✓
Europe	✓	2028	✓	2035	Pending	2037	Pending	✓
Germany	✓	2028	✓	2035	Pending	2037	Pending	-
Spain	✓	2028	✓	2035	Pending	2037	Pending	-
France	✓	2029	✓	2035	Pending	2037	Pending	-
United Kingdom	✓	2028	✓	2035	Pending	2037	Pending	-
Italy	✓	2028	✓	2035	Pending	2037	Pending	-
Sweden	✓	2028	✓	2035	Pending	2037	Pending	-
Japan	✓	2028	✓	2035	✓	2037	Pending	✓
China	✓	2028	Pending	2035	Pending	2037	Pending	✓

Recce Pharmaceuticals Ltd - Capital Structure

Major Shareholders – 26 Nov 2020	
G & O Melrose*	23.6%
LDU Pty Ltd	4.2%
HSBC Nominees	3.6%
J Graham**	3.5%
JP Morgan Nominees	2.7%



*4,614 holders as at 27/11/20

RCE 12 Month Snapshot

Share Price
335% Increase

Shareholder Base
182% Increase

Top 20 Holder Movement
5.3% greater holding than 12mths ago

Website Users
140% Increase

Twitter
64% Increase

LinkedIn
101% Increase

recce.com.au

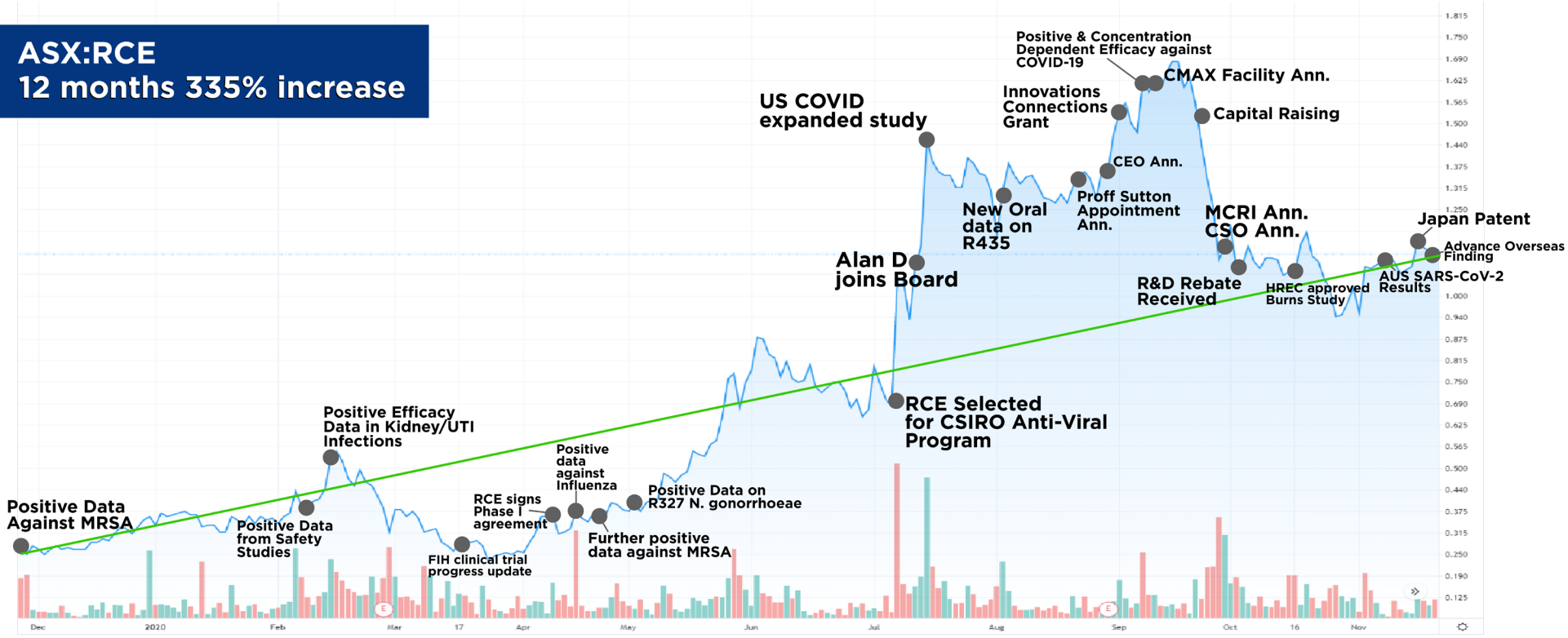
Snapshot

ASX code	**RCE**
Shares on issue 26 November 2020	**173.63 million**
Share price 26 November 2020	**AUD $1.13**
Market Cap (approx.) 26 November 2020	**AUD $196.2 million**
Cash and deposits 30 September 2020	**AUD $25.7 million**
Trading range 52 week	**AUD 0.21c - $1.875**
Average daily volume 3 months	**514.6K**
Debt	**Nil**

** Inventor & Former Head of J&J Research (Australasia)*
*** Held by Executive Directors*

Share price Movement – 12 months

ASX:RCE
12 months 335% increase



12 Months of Announcements

Since our last AGM:

- Positive Data for RECCE 327 in MRSA Burns Wound Infection **(27/11/19)**
- Positive Data from RECCE 327 Antibiotic Safety Studies **(10/02/20)**
- Positive Efficacy Data in Kidney/UTI Infections Animal Model **(14/02/20)**
- First-in-Human Clinical Trial Progress Update **(17/03/20)**
- Recce Signs Phase I Human Clinical Trial Agreement **(08/04/20)**
- Positive Data on RECCE 327 Against Influenza A **(20/04/20)**
- Further Positive Data on RECCE 327 Against MRSA Superbug **(23/04/20)**
- Positive Data on RECCE 327 Against *Neisseria gonorrhoeae* **(04/05/20)**
- RCE Selected by CSIRO/PDI for SARS-CoV-2 Antiviral Program **(08/07/20)**
- Recce Adds Biotech Veteran Alan Dunton MD to its Board **(14/07/20)**
- US Researchers to test RECCE in Expanded SARS-CoV-2 Program **(16/07/20)**
- Opening Address at 2020 World AMR Congress **(23/07/20)**
- Positive Oral Data on New RECCE 435 Against *H. pylori* **(04/08/20)**
- Appointment of *H. pylori* Expert Prof Sutton to Development Program **(21/08/20)**
- Recce Appoints James Graham as CEO **(28/08/20)**
- Recce Receives Innovation Connections Grant **(01/09/20)**
- Positive and Concentration-Dependent Efficacy Against COVID-19 **(08/09/20)**
- RECCE 327 Phase I Study – Australia's CMAX Clinical Facility **(10/09/20)**
- Recce Completes Capital Raising of $27.95m **(23/09/20)**
- MCRI Agreement – R435 against *H. pylori* **(30/09/20)**
- Recce Appoints Michele as CSO **(30/09/20)**
- HREC Approval to Start Ph I/II Burns Wound Study **(16/10/20)**
- Encouraging Results Against SARS-CoV-2 Virus **(10/11/20)**

6 months* Ahead – Global Infectious Disease Crisis!

Clinical

- **Phase I (R327) intravascular (I.V.) Safety Studies –** multiple news flow events
- **Phase I/II (R327) spray-on antibiotic burn wound studies –** parallel to I.V. program with world-first potential

Pre-Clinical

- **R327 COVID CSIRO/Doherty –** Advanced to next stage
- **R327 & R529 COVID (US) –** 'gold standard' ferret animal study model
- **Murdoch Children's Research Institute** - *H. Pylori in-vivo* studies
- **Mechanism of Action studies –** so it's unique? How so and what might it all mean

Corporate

- **Continue big-pharma discussions** – position of power with unique MoA & strong cash position
- **Expand international awareness** – particular focus on USA
- **Intellectual Property will continue to strengthen** – Patent Portfolio & Regulatory Incentive Focused
- **Further R&D Rebate** – Additional R&D rebate expected

**For illustrative purposes only – may not be representative of all activities in respective areas of business during this time*

Thank you

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